

K252549 Non-sterile Powder Free Nitrile Examination Glove, Dual Color (White-Green), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Xylazine HCl, and Simulated Gastric AcidJan 13, 2026
153 days to decisionK252549 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k252549/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 13, 2025
Decision date	Jan 13, 2026
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Non-sterile Powder Free Nitrile Examination Glove, Dual Color (White-Blue), Tested for Use with Chemotherapy Drugs, Fentanyl Citrate, Xylazine HCl, and Simulated Gastric Acid

APPLICANT

Company	Kossan International Sdn Bhd
Location	Klang, MY
Contact	Cho Sow Fong
510(k) history	12 submissions · 12 cleared · 2015-2026

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